DETAILED ACTION

Summary

1. Receipt of applicant's arguments and amended claims filed on 08/03/11 is acknowledged.

New claim 26 has been added.

Accordingly, claims **1-3 and 5-26** are under prosecution.

The rejections not reiterated herein have been withdrawn in light of claims amendments.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 5-10 and 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forward et al. (US 4,193,988) in view of Lee et al. (USP 6,214,321).

Forward et al. disclose oral hygiene compositions comprising a mixture of calcium glycerophosphate (calcium ion supplying compound) and sodium monofluorophosphate (a monofluorophosphate compound). The compositions may be formulated into powders, pastes, gels or liquids (Abstract). The activity of sodium

monofluorophosphate in reducing the solubility of tooth enamel is enhanced or potentiated when used in admixture with **certain proportions of calcium** glycerophosphate (col. 1, lines 22-26). The sodium monofluorophosphate and calcium glycerophosphate in the ratio of 10:1 to 3:1 are present in composition. The calcium glycerophosphate is at 0.2% and sodium monofluorophosphate is at 0.8%, see column 1, lines 64-65. The composition is in the form of paste, gel liquid or powder, abstract. The compositions may also comprise other calcium salts. The reference does not comprise phosphate ion supplying compound and as disclosed above the calcium ion supplying compound and monofluorophosphate ion supplying compounds are different. The liquids in the dental cream comprise chiefly water, glycerol and sorbitol (humectant). The amount is usually in range of 10%, preferable from 0.5% to 5.0% by weight of tooth paste, see column 2. A suitable surfactant can be added such as sodium lauryl sulfate, see column 2, lines 28-30 and examples. The pH of dental cream is of about 6 to 8, if desired a small amount of acid such as citric acid can be added, see column 2, lines 63-65. Various forms of composition can be mouth washes, chewing gum, lozenges, tablets, pastilles etc. see column 3, lines 7-13. The reference does not teach chelating agents (reads on the claimed 0.01% or less of chelating agent as claimed in instant claims 10 and 13).

While the reference suggests utilizing citric acid for pH adjustment, the reference does not teach utilizing the claimed lactic acid, malic or tartaric acid in the composition.

Lee et al. ('321) teaches remineralization of teeth comprising calcium salt such

as calcium phosphate and (calcium glycerophosphate) salts from amounts ranging from 0.01% to 30%, preferably from 0.1% to 20%, see title, column, 3 lines 10-15 and 30-32. The reference teaches that acidity of the composition can be adjusted with acids such as citric acid, lactic acid, malic acid or tartaric acid in an amount ranging from 0.1% to 20%, preferably from 0.5% to about 10%, see column 4, lines 10-20.The second composition comprises monofluorophosphate such as sodium and stannous and sodium fluoride which provides fluoride ions from about 25 to 5000 ppm of fluoride ions, see column 3, lines 53-55. The composition can be in the form of tooth paste, gel, powder or mouth wash, see column 3, lines 62-64. The first composition has lactic or malic acid or acid salts may also be applied. See column 4, lines 12-14. Humectants such as sorbitol, mannitol and maltitol are disclosed in column 4, lines 26-33.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to have utilized lactic acid or malic acid or tartaric acid in the composition of Forward et al. because Lee teaches equivalency among various acids which are used as pH regulating agents. Utilization of known pH adjusting agent such as lactic acid or malic acid would have been obvious to one of ordinary skill in the composition of Forward et al. with an expectation of obtaining predictable results, in the instant case utilization of lactic acid for pH adjustment would have been obvious to one of ordinary skill in the art. Regarding the claimed property of the composition that the composition does not settle and does not precipitate crystals after storage at 40 degrees Celsius for two weeks and has a residual factor of calcium ions of 76% or more after storage at 50 degrees Celsius for one month, it is reasonable to conclude that the compositions of the

combined teachings will have substantially similar properties because the compositions of the reference may comprise substantially the same components, a calcium ion supplying compound, a monofluorophosphate ion supplying compound of the instant claims and therefore upon mixing the two components calcium glycerophosphate and monofluorophosphate similar product will be formed comprising substantially similar properties as claimed. Since the claimed components of the oral composition are obvious in light of the teachings of prior art, one would expect the properties to be similar as claimed absent evidence to contrary.

It is to be noted that while the prior art by Forward and Lee teach inclusion of calcium glycerophosphate in the composition, however, the references do not state the instantly claimed calcium ions to be from 100 to 16000 ppm. To that end, the reference of Lee teaches the amount of calcium supplying compounds to be from 0.1% to 20% as discussed above, since the instant specification uses 1% of calcium ion supplying compound in Table 1 on page 12, it is the position of the Examiner that prior art's range of calcium ion supplying compound that is from 0.1% to 20% will supply the claimed amount of calcium ions that is from 100 to 16000 ppm absent evidence to contrary. (It is to be noted that it is known in the dental art for remineralization that monofluorophosphate supplies monofluorophosphate ion first and then fluoride ion, it is the fluoride ion that is measured to check the concentration in ppm for monofluorophosphate compounds, USP PG pub. 20060099153, see paragraph [0021] and US PG pub. 20030170185, see examples 31-32 under ingredients under sodium monofluorophosphate, the concentration in terms of fluoride ion is 950 ppm.). Thus

since the prior art teaches the calcium ion supplying compound, optimization of amount of such compound for the optimum release of calcium ions would have been obvious to one of ordinary skill by performing experimental manipulations. Regarding amount of various calcium or sodium monofluorophosphate, reference teaches various amounts as discussed above, experimentation with workable amounts in order to obtain best possible results would have been obvious over the teachings of prior art absent indication of unexpected results especially in light of Forwards teachings that the activity of sodium monofluorophosphate in reducing the solubility of tooth enamel is enhanced or potentiated when used in admixture with **certain proportions of calcium** glycerophosphate (col. 1, lines 22-26) as discussed above.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forward et al. (US 4,193,988) in view of Lee et al. (USP 6,214,321) as discussed above and further in view of (Takatsuka et al. (USP 7,300,645).

The references discussed above do not teach using silicic anhydride in composition. Takatsuka et al. while teaching oral composition for remineralizing

properties teach inclusion of silicic anhydride in the tooth paste formulation, see examples 21-22.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to have incorporated art recognized ingredients in tooth paste formulation contemplated in light of teachings of Forward and Lee et al. One of ordinary would have been motivated to do so because Takatsuka teaches a tooth paste formulation comprising silicic anhydride which is intended to be used for remineralization of tooth. Utilization of known ingredient would have resulted in predictable results that are a tooth paste composition with better remineralization properties absent evidence to contrary.

Response to Arguments

5. Applicant's arguments filed 08/31/11 have been fully considered but they are not persuasive.

Applicant argues that the present application describes an invention in which a chelating agent (e.g., citrate) is preferably not substantially added. In this aspect of the invention, *avoiding* the chelating agent prevents the decrease of calcium ion concentration. This in turn allows improved remineralization of teeth (see paragraphs [0012] and [0016] of the PG publication (i.e., US 2007/0128131)).

These arguments are not persuasive because the instant claims do recite presence of chelating agent in an amount of 0.1% by weight, while the arguments are true for no presence of chelating agent such as citrate, the results discussed do not

commensurate with entire scope of all the chelating agents and with the amount claimed that is 0.1%.

Applicant argues that the Forward patent describes a different composition; namely, a composition in which pH is controlled by *adding* substances such as citric acid (see column 2, lines 62-65 of the Forward patent). Forward does not appreciate and does not disclose the difficulties encountered when sodium monofluorophosphate is used in combination with calcium glycerophosphate and thus does not appreciate the chelate-avoidance aspect of the present invention. Applicants on the other hand disclosed the difficulties associated with using sodium monofluorophosphate in admixture with a calcium ion-supplying compound (see for example paragraphs [0003] and [0011] of the PG publication). Citric acid in particular binds strongly to calcium ions to thereby chelate the calcium ion and make the calcium unavailable for the purpose of remineralizing teeth. The invention described in the present claims avoids this undesirable function of chelation by requiring that chelating agents such as citrate (e.g., a salt or ester derived from citric acid) are included in an amount of no more than 0.1 wt.%. This requirement of the present claims is directly contradictory to the Forward disclosure in which citric acid (e.g., a progenitor of the citrate chelating agent) is added to control pH (see column 4, second paragraph of Forward). Applicants disclosed a composition which permits the stable supply of calcium ions for the remineralization of teeth by using a particular acid to control the pH to 4-6.2. Forward describes modifying the acidity of compositions with an acid agent (e.g., citrate). In contrast, the present claims restrict the amount of chelating agent (e.g., citrate) to no more than 0.1%.

These arguments are not persuasive because the instant claims recite presence of chelating agent in 0.1% and thus read on prior art's agent. Besides as discussed above the remineralization improvement results discussed by applicants do not commensurate with scope of instant claims because claims recite presence of chelating agent in addition to being devoid of chelating agent. The prior art teaches and makes obvious the claimed invention, motivation to combine the prior art's teachings need not be same as applicants motivation for the invention. A comparative analysis with scientific and technical results to prove unexpected results has not been provided which results also commensurate with the entire scope of claims; as such the rejection is maintained. The results discussed are with only specific chelating agent citrate whereas instant claims encompass various chelating agents and reads on any amount less than 0.1%. Regarding Lee, Lee has been combined for modifying acidity of the composition with lactic, malic or tartaric acid. As discussed earlier applicant's motivation to use specific pH need not be same as motivation to combine in an obvious manner, in the instant case Lee teaches lactic acid etc. for modifying pH and modification of pH or adjustment of pH to obtain best possible results would be with in skill of an artisan.

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., **In re Kahn**, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Regarding Lee, applicant argues that Lee fails to remedy the defects of Forward. It is an explicit requirement of the present claims that the claimed composition is "homogeneous". Lee describes a composition that must be in separate parts (see the Abstract of Lee). Importantly, at least one of the components of the Lee composition must have a pH that is outside of the pH range recited in the present claims (see the Abstract of Lee). Further, even if the separate portions of the Lee composition were combined, the resulting composition would violate the "homogeneous" requirement of the present claims because hydroxyapatite precipitates (see the Abstract of Lee).

These arguments are not persuasive because Lee has been combined to show equivalency among various acid for adjusting pH of oral composition.

Applicant argues in pages 13-14 that neither Forward nor Lee recognize the problem associated with the presence of chelating agents, including citrate. The discovery of a problem is often the key to making a patentable invention. Thus, the patentability of an invention under 35 U.S.C. § 103 must be evaluated against the background of the highly developed and specific art to which it relates, and this background includes an understanding of those unsolved problems persisting in the art solved by the invention.

These arguments are not persuasive because instant claims are drawn to composition claims and the claimed composition is obvious over prior art, as discussed a earlier, the argued differences are not reflected in instant claims and also the results discussed do not commensurate with scope of instant claims. Rationale for combining teachings of prior art need not be same as applicant's motivation to add specific

ingredients. Regarding Lee, applicant argues on pages 14 and 15 that the composition is not homogeneous and argues that claims 22-23 describe compositions in which the calcium ion-supplying compound is present in a greater amount than the monofluorophosphate ion-supplying compound. Claims 22 and 23 are further patentable over the combination of Forward and Lee for the reason that Forward describes compositions in which a calcium-containing material is present in substantially greater amounts than a monofluorophosphate-containing compound, i.e., a composition in which sodium monofluorophosphate and calcium glycerophosphate are present in relative amounts of 10:1 to 3:1. In Lee the sodium monofluorophosphate is present in substantially greater amounts than the calcium glycerophosphate (see the Abstract of Forward). New Claims 24 and 25 further define the relative amounts of the monofluorophosphate ion-supplying and calcium ion-supplying compounds of the present claims.

These arguments are not persuasive , as discussed above Lee has been combined for use of acids and use of various amounts of sodium monofluorophosphate and calcium glycerophosphate, Forward teaches that the activity of sodium monofluorophosphate in reducing the solubility of tooth enamel is enhanced or potentiated when used in admixture with **certain proportions of calcium** glycerophosphate (col. 1, lines 22-26). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*

Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that claims 20 and 21 are patentable over the cited art. Where Forward describes a pH range that is 6 or greater (see column 2, lines 62-65), Claims 20 and 21 describe pH ranges that do not include a pH of 6. Applicants thus submit that Claims 20 and 21 are further patentable over the cited art.

The examiner does not agree because it is customary in dental art to adjust pH for oral application, no criticality is seen with such limitation where prior art teaches use of citric, lactic or tartaric acid to modify pH. Applicants did not specifically argue merits of Takatsuka used for remineralization with silicic anhydride.

The following rejection is necessitated by claim amendments.

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takatsuka et al. (USP 6,471,946).

Takatsuka et al. discloses an oral composition that enhances remineralization, (column 1, and lines 45-46). Takatsuka et al. teaches use of calcium compounds such as calcium glycerophosphate, calcium lactate as remineralization agent, (column 3, and lines 15-16). The reference teaches use of sodium and potassium monofluorophosphate as fluorine compounds and the amount in oral composition ranges from 0.1-5000ppm, (column 2, lines 36-37 and lines 40-44). The humectants such as sorbitol, glycerol to be added in composition are taught in column 3, lines 45-

47. The pH of the composition is disclosed from 6.0 to 8.5 in column 3, lines 1-3. The pH adjusting agents are citric acid, malic acid, lactic acid or salts thereof, (column 4, lines 5-15). Example 19 teaches citric acid in 0.1% and Example 22 teaches malic acid in amount of 0.2%. The reference teaches example 21 with no phosphate ions and no chelating agents. The amount of citric acid shown in example 19 reads on the claimed amount of 0.1% or less as claimed in instant claim 1. The reference does not teach aluminum compound in examples. Sodium lauryl sulfate in taught in example 28.

The specific combination of features claimed is disclosed within the broad genera of ingredients and forms taught by Takatsuka et al. but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro, 425 U.S. 273,282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not

seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning, it would have been *primafacie* obvious to one of ordinary skill in the art at the time the invention was made to have selected various combinations of ingredients and forms from within the disclosure of Takatsuka et al. to arrive at compositions "yielding no more than one would expect from such an arrangement". It would be obvious to one of ordinary skill to use calcium glycerophosphate, sodium monofluorophosphate for remineralization with a reasonable expectation of success.

Regarding claim 26 which recites no presence of chelating agent, it is reasonable to conclude that while the reference teaches in example 19 inclusion of 0.1% citric acid, the reference also at the same time teaches example 21 for oral composition with no phosphates and no chelating agents, as such it would be obvious to one of ordinary skill to have excluded the phosphate salts or chelating agents if the property of the ingredient was not desired, particularly in light of the teachings of state of the art that includes or excludes chelating agents as discussed above.

Cited as of interest

Takatsuka (as discussed above teaches all the claimed limitations and makes obvious not to include chelating agents, as such the argued properties would be apparent with Takatsuka's reference (USP 6,471,946) as discussed above)

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

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